

Message

From: Carolyn R Klocke [crklocke@ucdavis.edu]
Sent: 5/18/2018 4:08:02 PM
To: Pamela Lein [pjlein@ucdavis.edu]; Lehmann, Geniece [Lehmann.Geniece@epa.gov]; Joanne Trgovcich [Joanne.Trgovcich@icf.com]; Carlson, Laura [Carlson.Laura@epa.gov]; Taylor, MicheleM [taylor.michelem@epa.gov]; Burch, Dave [dave.burch@icf.com]; Robins, Sean [Sean.Robins@icf.com]
Subject: RE: Review Guidelines for evaluating animal studies of neurobehavioral outcomes for the IRIS PCB assessment

Wonderful, thanks Geniece!

Cheers,
Carrie

From: Pamela J Lein
Sent: Friday, May 18, 2018 9:06 AM
To: Lehmann, Geniece <Lehmann.Geniece@epa.gov>; Carolyn R Klocke <crklocke@ucdavis.edu>; Joanne Trgovcich <Joanne.Trgovcich@icf.com>; Carlson, Laura <Carlson.Laura@epa.gov>; Taylor, MicheleM <taylor.michelem@epa.gov>; Burch, Dave <dave.burch@icf.com>; Robins, Sean <Sean.Robins@icf.com>
Subject: RE: Review Guidelines for evaluating animal studies of neurobehavioral outcomes for the IRIS PCB assessment

Thanks Geniece – this is very helpful.

We'll get our feedback to you by the May 31 deadline.

Pam

From: Lehmann, Geniece [<mailto:Lehmann.Geniece@epa.gov>]
Sent: Friday, May 18, 2018 8:59 AM
To: Carolyn R Klocke <crklocke@ucdavis.edu>; Joanne Trgovcich <Joanne.Trgovcich@icf.com>; Carlson, Laura <Carlson.Laura@epa.gov>; Pamela J Lein <pjlein@ucdavis.edu>; Taylor, MicheleM <taylor.michelem@epa.gov>; Burch, Dave <dave.burch@icf.com>; Robins, Sean <Sean.Robins@icf.com>
Subject: RE: Review Guidelines for evaluating animal studies of neurobehavioral outcomes for the IRIS PCB assessment

Hi Carrie and Pam,

I didn't forget about you! After our meeting on Wednesday, I decided to try to provide a little more information to help you understand what we're looking for with regard to the criteria. So, it took some time, but I'm hoping that this will make it easier for you to make recommendations and for us to implement them.

Ex. 5 Deliberative Process (DP)

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Replying to comments as needed:

We'll plan on having these materials back to us by **May 31**, including any additional input you may receive from your colleagues.

Please let me know if you have any questions or would like to discuss further.

Thanks,
Geniece

Geniece M. Lehmann, Ph.D.
Toxicologist
National Center for Environmental Assessment
Office of Research & Development
U.S. Environmental Protection Agency, B243-01
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From: Carolyn R Klocke [<mailto:crklocke@ucdavis.edu>]

Sent: Wednesday, May 16, 2018 2:40 PM

To: Lehmann, Geniece <Lehmann.Geniece@epa.gov>; Joanne Trgovcich <Joanne.Trgovcich@icf.com>; Carlson, Laura <Carlson.Laura@epa.gov>; Pamela Lein <pjlein@ucdavis.edu>; Taylor, MicheleM <taylor.michelem@epa.gov>; Burch, Dave <dave.burch@icf.com>; Ali Goldstone <Ali.Goldstone@icf.com>; Robins, Sean <Sean.Robins@icf.com>; Blain, Robyn <Robyn.Blain@icf.com>; Sorina Eftim <sorina.eftim@icf.com>; Ross, Pam <Pam.Ross@icf.com>

Subject: RE: Review Guidelines for evaluating animal studies of neurobehavioral outcomes for the IRIS PCB assessment

Hi all,

Attached are completed evaluation criteria and reporting for discussion at today's meeting. Apologies for sending them right before, but we would love any feedback on how they're filled out, etc.

Talk to you all soon!

Carrie

Carolyn R. Klocke, MS, PhD

Department of Molecular Biosciences

School of Veterinary Medicine (VM3B)

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-----Original Appointment-----

From: Lehmann, Geniece <Lehmann.Geniece@epa.gov>

Sent: Friday, April 6, 2018 1:50 PM

To: Joanne Trgovcich; Carlson, Laura; Pamela J Lein; Taylor, MicheleM; Burch, Dave; Ali Goldstone; Robins, Sean; Blain, Robyn; Sorina Eftim; Ross, Pam; Carolyn R Klocke

Subject: Review Guidelines for evaluating animal studies of neurobehavioral outcomes for the IRIS PCB assessment

When: Wednesday, May 16, 2018 3:00 PM-4:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: RTP-B230-Max20-NCEA/RTP-Bldg-B

Attaching a draft PECO statement for the first-tier priority neurological outcomes that will be the subject of our first systematic review. Hopefully, this will help everyone to see how the development of the PECO statement flows from the work we've been doing to categorize outcomes.

Pam and Carrie will be asked to review, revise and complete the table of "First-tier priority outcomes measured in studies of animals exposed to complex PCB mixtures". Much of the information needed to complete that table will be gathered as a part of the work that ICF, Pam, and Carrie are already planning to do over the next month or so. For now,

nothing special needs to be done with it. We can discuss next steps at the meeting on May 16. I'm just providing it here so that you'll have some sense of the direction we're headed in.

Hi All,

Attached are materials to help us prepare for our discussion on May 16. We're transitioning now from the clunky "template" document to a less-clunky (I hope) "guidelines" document that should be closer to what evaluators will really be using when we conduct study quality evaluations.

- Much of the material from the template document has been moved forward into the "new" document (Neurological Effects – SQE criteria_tox).
- I've also attached the original template document so that you can monitor the discussions that resulted from the first round of review and pilot exercise.
- There may be comments of interest to you in both documents.

Comments with the word "TEAM" highlighted are discussion points for our meeting on May 16. Please be prepared to discuss these issues at the meeting.

Also: We're preparing materials to support Pam Lein's effort to gather more specific information on the most commonly-administered tests of behaviors related to cognition and/or emotional state in the PCB database.

- Appendix A in the Neurological Effects – SQE criteria_tox document contains a table where we will collect the information from that effort.
- Each column represents a question raised during our pilot exercise for which we would like to have test-specific information.
- I would like to make sure that we've covered all of our major questions in that table so that Pam will be able to focus the efforts of her group on the questions most important to us for study quality evaluation.
- Please take a look at Appendix A and send me any suggested revisions or additional questions for the experts **no later than April 12**. That will give us time to get the relevant questions to Pam and will give her time to collect the answers before our meeting in May.

Note to Pam: we don't expect there to be answers to every question for every test. We're most interested in factors that could have a significant impact on study results (i.e. whether or not a study identifies an effect of PCB exposure).

Thanks,
Geniece

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